



Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimbalà
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
Donald J. Featherstone
Timothy J. Shea, Jr.
Michael V. Messinger
John U. Kim

Patrick E. Garrett
Jeffrey I. Helvey
Heidi L. Kraus
Eldora L. Ellison
Thomas C. Fiala
Albert L. Ferro
Donald R. Banowitz
Peter A. Jackman
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Brian J. Del Buono
Virgil Lee Beaton
Theodore A. Wood
Elizabeth J. Haanes
Joseph S. Ostroff
Frank R. Cottingham
Rae Lynn P. Guest
Daniel A. Klein

Jason D. Eisenberg
Michael D. Specht
Andrea J. Kamage
Tracy L. Muller
Jon E. Wright
LuAnne M. DeSantis
Ann E. Summerfield
Aric W. Ledford
Helene C. Carlson
Cynthia M. Bouchez
Timothy A. Doyle
Gaby L. Longworth
Lori A. Gordon
Nicole D. Dretar
Ted J. Ebersole
Laura A. Vogel
Michael J. Mancuso
Bryan S. Wade
Aaron L. Schwartz

Shannon A. Carroll*
Wesley W. Jones*
Matthew E. Kelley*
Michelle K. Holoubek*
Marsha A. Rose*

Registered Patent Agents*
Karen R. Markowicz
Nancy J. Leith
Matthew J. Dowd
Katrina Yujian Pei Quach
Bryan L. Skelton
Robert A. Schwartzman
Teresa A. Colella
Victoria S. Rutherford
Simon J. Elliott
Julie A. Heider
Mita Mukherjee

Scott M. Woodhouse
Christopher J. Walsh
Liliana Di Nola-Baron
Peter A. Socarras
Jeffrey Mills

Of Counsel
Kenneth C. Bass III
Marvin C. Guthrie

*Admitted only in Maryland
*Admitted only in Virginia
*Practice Limited to
Federal Agencies

August 31, 2005

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

WRITER'S DIRECT NUMBER:

(202) 772-8560

INTERNET ADDRESS:

RESMOND@SKGF.COM

Art Unit 1614

Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/814,633; Filed: April 1, 2004
For: **Solution Based Methacholine Formulations**
Inventor: Van Hung Truong
Our Ref: 2201.0020000/RWE

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO/SB/08A (1 sheet);
3. Form PTO/SB/08B (2 sheets) and accompanying (17) references; and
4. Return postcard.

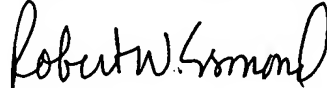
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
August 31, 2005
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicant
Registration No. 32,893

RWE/dab
438686_1.DOC
Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Van Hung Truong

Appl. No.: 10/814,633

Filed: April 1, 2004

For: **Solution Based Methacholine
Formulations**

Confirmation No.: 7438

Art Unit: 1614

Examiner: (to be assigned)

Atty. Docket: 2201.0020000/RWE

Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents NPL1-NPL17 are submitted. However, no copy of the cited U.S. patent is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application or before the mailing date of a first Office Action on the merits. No statement or fee is required.

Documents NPL3-NPL5, NPL9, NPL13 and NPL15-NPL17 were cited in a search report by a foreign patent office in a counterpart foreign application. The search report is cited herein as Document NPL10 and a copy thereof is provided. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

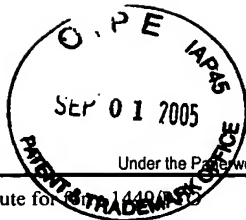


Robert W. Esmond
Attorney for Applicant
Registration No. 32,893

Date: August 31, 2005

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

438519_1.DOC



Equivalent of Form PTO/SB/08A (07-05)

Approved for use through 07/31/2006.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/814,633
				Filing Date	April 1, 2004
				First Named Inventor	Van Hung Truong
				Art Unit	1614
				Examiner Name	(to be assigned)
Sheet	1	of	1	Attorney Docket Number	2201.0020000/RWE

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	US1	2,040,145	05-12-1936	Major, R.T. <i>et al.</i>	
	US2				
	US3				
	US4				
	US5				
	US6				
	US7				
	US8				
	US9				
	US10				
	US11				
	US12				
	US13				
	US14				
	US15				
	US16				
	US17				
	US18				
	US19				
	US20				

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	FP1					
	FP2					
	FP3					
	FP4					
	FP5					
	FP6					
	FP7					
	FP8					
	FP9					

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/814,633
				Filing Date	April 1, 2004
				First Named Inventor	Van Hung Truong
				Art Unit	1614
				Examiner Name	(to be assigned)
Sheet	1	of	2	Attorney Docket Number	2201.0020000/RWE

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T ²
	NPL1	Acar, V. <i>et al.</i> , "Stability of stored methacholine solutions: study of hydrolysis kinetic by IP-LC," <i>J. Pharmaceut. Biomed. Anal.</i> 25:861-869 (2001)	
	NPL2	American Thoracic Society: "Guidelines for Methacholine and Exercise Challenge Testing - 1999," <i>Am. J. Respir. Crit. Care Med.</i> 161:309-329 (2000)	
	NPL3	Amersham Biosciences. "Reverse Phase Chromatography: Principles and Methods"; Chapter 3, "Methods"; pp. 41-56. Published February 1999 (Document available on internet at http://www.ls.huji.ac.il/-purification/PDF/ReversePhase/AmershamRPCManual.pdf)	
	NPL4	Asmus, M.J. <i>et al.</i> , "Stability of Frozen Methacholine Solutions in Unit-Dose Syringes for Bronchoprovocation," <i>CHEST</i> 121:1634-1637 (May 2002)	
	NPL5	Boehm, J.J. <i>et al.</i> , "Shelf life of unrefrigerated succinylcholine chloride injection," <i>Am. J. Hosp. Pharm.</i> 41:300-302 (1984)	
	NPL6	Cockroft, D.W. <i>et al.</i> , "Bronchial reactivity to inhaled histamine: a method and clinical survey," <i>Clin. Allergy</i> 7:235-243 (1977)	
	NPL7	Cockroft, D.W. <i>et al.</i> , "Determination of Histamine PC ₂₀ : Comparison of Linear and Logarithmic Interpolation," <i>CHEST</i> 84:505-506 (1983)	
	NPL8	Hargreave, F.E. <i>et al.</i> , "Bronchial responsiveness to histamine or methacholine in asthma: measurement and clinical significance," <i>J. Allergy Clin. Immunol.</i> 68:347-355 (1981)	
	NPL9	Hayes, R.D. <i>et al.</i> , "Stability of methacholine chloride solutions under different storage conditions over a 9 month period," <i>Eur. Respir. J.</i> 11:946-948 (1998)	
	NPL10	International Search Report for corresponding International Application No. PCT/CA2005/000496, filed April 1, 2005, five pages, Canadian Intellectual Property Office, mailed July 19, 2005	

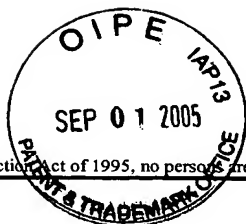
Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/814,633
				Filing Date	April 1, 2004
				First Named Inventor	Van Hung Truong
				Art Unit	1614
				Examiner Name	(to be assigned)
Sheet	2	of	2	Attorney Docket Number	2201.0020000/RWE

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL11	Juniper, E.F. <i>et al.</i> , "Histamine and Methacholine Inhalation Tests: Tidal Breathing Method, Laboratory Procedure and Standardisation," 52 pages, Canadian Thoracic Society, Astra Draco AB, Lund, Sweden (1994)	
	NPL12	Rosenfeld, J. <i>et al.</i> , "Gas chromatographic determination of methylcholine chloride in pharmaceutical preparations," <i>J. Chromatog.</i> 287:433-437 (1984)	
	NPL13	van der Schans, M.J. <i>et al.</i> , "Quality control of histamine and methacholine in diagnostic solutions with capillary electrophoresis," <i>J. Chromatog. A</i> 735:387-393 (1996)	
	NPL14	Wanger, J.S. <i>et al.</i> , "The Stability of Reconstituted Commercial Methacholine (Provocholine®)," American Thoracic Society International Annual Meeting held in Seattle, Washington, May16-21, 2003. A046 [Poster E32]	
	NPL15	Watson, B.L. <i>et al.</i> , "Effect of pH on the stability of methacholine chloride in solution," <i>Respir. Med.</i> 92:588-592 (1998)	
	NPL16	(Website) "Practical Engineering Data & Tools for Medical Device Professionals: Selecting a Sterilization Method," 4 pages, Sungate Technologies Incorporated (2001). Available at http://www.engineeringreference.com/Sterlization/select%20sterilization.htm	
	NPL17	Woodman, T.F. <i>et al.</i> , "Determination of Methacholine Chloride by Ion-Pair High-Pressure Liquid Chromatography," <i>J. Liquid Chromatog.</i> 5:1341-1348 (1982)	
	NPL18		
	NPL19		

438528_1.DOC

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.